

## REMARKS

Claims 1-56 are currently pending in the application. Claims 7, 11-48, and 51-56 have been withdrawn from consideration in response to a restriction requirement. In response to an election of species requirement, the following species have been elected for initial search and examination in the application: (1) compound species: compound of Example 5, 6-[(2-{[6-(2,4-dichlorophenyl)-5-imidazolyl-2-pyridyl]amino}ethyl)amino]pyridine-3-carbonitrile (CT 99025); (2) additional agent: "absence of additional agent"; and (3) route of administration: "subcutaneous administration." Claims 7, 11-48, and 51-56 have been withdrawn from further consideration as being drawn to nonelected subject matter. Claims 1-6, 8-10, 49, and 50 have been examined as far as they read upon the elected species, and stand rejected.

It is believed that Claims 1-6, 8-10, 49, and 50 are in condition for allowance in view of the foregoing amendments and following comments. Reconsideration is requested.

### Rejection Under 35 U.S.C. § 112

Claims 1-6, 8-10, 49, and 50 have been rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. It is the Examiner's view that the specification, while being enabling for the treatment of ischemic brain injury, does not provide enablement for prevention of ischemic injury with the GSK3 inhibitor CT-99025 of Example 5. Without acquiescing to the Examiner's position, but in order to advance prosecution, independent Claim 1 has been amended to recite:

1. A method for the treatment of a human or animal subject comprising administering to the subject within 24 hours of the onset of an ischemic stroke event an amount of a glycogen synthase kinase 3 (GSK3) inhibitor effective to reduce ~~or prevent~~ ischemic stroke injury in the subject."

In view of the foregoing amendment, this rejection is believed to be moot. Removal of this ground of rejection is respectfully requested.

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Rejection Under 35 U.S.C. § 102(e)

Claims 1-6, 8-10, 49, and 50 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Nuss et al., U.S. Patent No. 7,045,519 (hereinafter the "Nuss et al. '519 patent"). This rejection is respectfully traversed.

The present invention relates to the treatment of ischemic stroke by administering an effective amount of a GSK3 inhibitor within 24 hours of the onset of an ischemic stroke event. The Nuss et al. '519 patent discloses that GSK3 inhibitors may be useful in treating disorders such as ischemia. However, the Nuss et al. '519 patent does not teach or suggest a treatment regime as set forth in Claims 1-3 of the present application, namely, the administration of a GSK3 inhibitor within 24 hours, 8 hours, or 2 hours of the onset of the ischemic stroke event. Similarly, the Nuss et al. '519 patent does not teach or suggest the administration of a GSK3 inhibitor intermittently or continuously for at least 24 hours, as recited in Claim 4. Therefore, because the Nuss et al. '519 patent does not teach or suggest all the elements of independent Claim 1, or dependent Claims 2-6, 8-10, 49, and 50, the Nuss et al. '519 patent does not anticipate the invention of Claim 1 as a matter of law. Removal of this ground of rejection is respectfully requested.

Rejection Under 35 U.S.C. § 103(a)

Claims 1-6, 8-10, 49, and 50 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over the Nuss et al. '519 patent, described above. This rejection is respectfully traversed.

As noted by the Examiner, the Nuss et al. '519 patent constitutes prior art only under 35 U.S.C. § 102(e). As detailed in the attached "Statement Overcoming Commonly Owned Prior Art," the instant application and the Nuss et al. '519 patent were, at the time the invention of the

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instant application was made, owned by Chiron Corporation of Emeryville, California. Therefore, removal of this ground of rejection is respectfully requested.

The Double Patenting Rejection

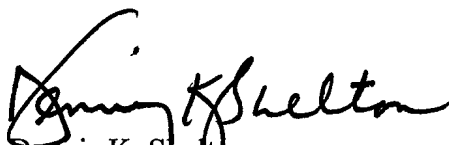
Claims 1-6, 8-10, 49, and 50 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 39-44 of the Nuss et al. '519 patent (described above). A terminal disclaimer in compliance with 37 CFR 1.321(c) is filed herewith.

Conclusion

In view of the foregoing amendments, the Statement Overcoming Commonly Owned Prior Art, and the terminal disclaimer submitted herewith, Claims 1-6, 8-10, 49, and 50 are believed to be in condition for allowance. Reconsideration and favorable action is requested. The Examiner is further requested to contact applicant's representative at the number set forth below to discuss any issues that may facilitate prosecution of the application.

Respectfully submitted,

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: S.D. Harrison et al. Attorney Docket No.: PP19016.003  
Application No.: 10/506570 Art Unit: 1614 / Confirmation No: 1325  
Filed: April 29, 2005 Examiner: A. A. Lewis  
Title: METHODS AND COMPOSITIONS FOR THE TREATMENT OF  
ISCHEMIA

STATEMENT OVERCOMING COMMONLY OWNED PRIOR ART

Emeryville, California 94608

February 26, 2009

TO THE COMMISSIONER FOR PATENTS:

In response to the Office communication mailed September, 2, 2008, please enter the following.

1. This application has been objected to under § 103/102 (e) on the basis of obviousness based on the citation as prior art of the following reference:

U.S. Patent No. 7,045,519 (Nuss et al.).

**Common Ownership**

2. Applicant requests that this objection be withdrawn because Application No. 10/506,570 and U.S. Patent No. 7,045,519 to Nuss et al. were, at the time the invention claimed in this application was made, owned by: Chiron Corporation, of Emeryville, California (now Novartis Vaccines and Diagnostics, Inc.).

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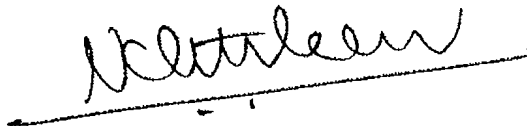
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**Terminal Disclaimer**

3. A terminal disclaimer in accordance with § 1.321(c) is filed herewith.

Respectfully submitted,

NOVARTIS VACCINES AND  
DIAGNOSTICS, INC.

A handwritten signature in black ink, appearing to read "Vinit Kathardekar", is written over a horizontal line.

Vinit Kathardekar  
Corporate Patent Counsel

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